§ 26.5 Definitions.

Acute fatigue means fatigue from causes (e.g., restricted sleep, sustained wakefulness, task demands) occurring within the past 24 hours.

Adulterated specimen means a urine specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent of urine or showing an abnormal concentration of an endogenous substance.

Alertness means the ability to remain awake and sustain attention.

Aliquot means a portion of a specimen that is used for testing. It is taken as a sample representing the whole specimen.

Analytical run means the process of testing a group of urine specimens for validity or for the presence of drugs and/or drug metabolites. For the purposes of defining the periods within which performance testing must be conducted by any licensee testing facility or HHS-certified laboratory that continuously processes specimens, an analytical run is defined as no more than an 8-hour period. For a facility that analyzes specimens in batches, an analytical run is defined as a group of specimens that are handled and tested together.

Authorization means that a licensee or other entity in §26.3 has determined that an individual has met the requirements of this part to be granted or maintain the types of access or perform the duties specified in §26.4(a) through (e), and, at the licensee's or other entity's discretion, §26.4(f) or (g).

Best effort means documented actions that a licensee or other entity who is subject to subpart C of this part takes to obtain suitable inquiry and employment information in order to determine whether an individual may be granted authorization, when the primary source of information refuses or indicates an inability or unwillingness to provide the information within 3 business days of the request and the licensee or other entity relies on a secondary source to meet the requirement.

Blood alcohol concentration (BAC) means the mass of alcohol in a volume of blood.

Calibrator means a solution of known concentration which is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest.

Category IA material means SSNM that is directly usable in the manufacture of a nuclear explosive device, except if the material meets any of the following criteria:

(1) The dimensions are large enough (at least 2 meters in one dimension, greater than 1 meter in each of two dimensions, or greater than 25 centimeters in each of three dimensions) to preclude hiding the item on an individual;

(2) The total weight of an encapsulated item of SSNM is such that it cannot be carried inconspicuously by one person (i.e., at least 50 kilograms gross weight); or

(3) The quantity of SSNM (less than 0.05 formula kilograms) in each container requires protracted diversions to accumulate 5 formula kilograms.

Chain of custody means procedures to account for the integrity of each specimen or aliquot by tracking its handling and storage from the point of specimen collection to final disposition of the specimen and its aliquots. "Chain of custody" and "custody and control" are synonymous and may be used interchangeably.

Circadian variation in alertness and performance means the increases and decreases in alertness and cognitive/motor functioning caused by human physiological processes (e.g., body temperature, release of hormones) that vary on an approximately 24-hour cycle.

Collection site means a designated place where individuals present themselves for the purpose of providing a specimen of their urine, oral fluids, and/or breath to be analyzed for the presence of drugs or alcohol.

Collector means a person who is trained in the collection procedures of

subpart E, instructs and assists a specimen donor at a collection site, and receives and makes an initial examination of the specimen(s) provided by the donor.

Commission means the U.S. Nuclear Regulatory Commission (NRC) or its duly authorized representatives.

Confirmatory drug or alcohol test means a second analytical procedure to identify the presence of alcohol or a specific drug or drug metabolite in a specimen. The purpose of a confirmatory test is to ensure the reliability and accuracy of an initial test result.

Confirmatory validity test means a second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Confirmed test result means a test result that demonstrates that an individual has used drugs and/or alcohol in violation of the requirements of this part or has attempted to subvert the testing process by submitting an adulterated or substituted urine specimen. For drugs, adulterants, and substituted specimens, a confirmed test result is determined by the Medical Review Officer (MRO), after discussion with the donor subsequent to the MRO's receipt of a positive confirmatory drug test result from the HHS-certified laboratory and/or a confirmatory substituted or adulterated validity test result from the HHS-certified laboratory for that donor. For alcohol, a confirmed test result is based on a positive confirmatory alcohol test result from an evidential breath testing device (EBT) without MRO review of the test result.

Constructing or construction activities mean, for the purposes of this part, the tasks involved in building a nuclear power plant that are performed at the location where the nuclear power plant will be constructed and operated. These tasks include fabricating, erecting, integrating, and testing safety- and security-related SSCs, and the installation of their foundations, including the placement of concrete.

Contractor/vendor (C/V) means any company, or any individual not employed by a licensee or other entity specified in § 26.3(a) through (c), who is providing work or services to a licensee or other entity covered in § 26.3(a) through (c), either by contract, purchase order, oral agreement, or other arrangement.

Control means a sample used to monitor the status of an analysis to maintain its performance within predefined limits.

Cumulative fatigue means the increase in fatigue over consecutive sleep-wake periods resulting from inadequate rest.

Cutoff level means the concentration or decision criteria established for designating and reporting a test result as positive, of questionable validity (referring to validity screening or initial validity test results from a licensee testing facility), or adulterated, substituted, dilute, or invalid (referring to initial or confirmatory test results from an HHS-certified laboratory).

Dilute specimen means a urine specimen with creatinine and specific gravity concentrations that are lower than expected for human urine.

Directing means the exercise of control over a work activity by an individual who is directly involved in the execution of the work activity, and either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity.

Donor means the individual from whom a specimen is collected.

Eight (8)-hour shift schedule means a schedule that averages not more than 9 hours per workday over the entire shift cycle.

Employment action means a change in job responsibilities or removal from a job, or the employer-mandated implementation of a plan for substance abuse treatment in order to avoid a change in or removal from a job, because of the individual's use of drugs or alcohol.

Fatigue means the degradation in an individual's cognitive and motor functioning resulting from inadequate rest.

Formula quantity means SSNM in any combination in a quantity of 5000 grams or more computed by the formula, grams=(grams contained U–235)+2.5 (grams U–233+grams plutonium). This class of material is sometimes referred to as a Category I quantity of material.

HHS-certified laboratory means a laboratory that is certified to perform

urine drug testing under the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (the HHS Guidelines), which were published in the FEDERAL REGISTER on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13, 1998 (63 FR 63483), and April 13, 2004 (69 FR 19643).

Illegal drug means, for the purposes of this regulation, any drug that is included in Schedules I to V of section 202 of the Controlled Substances Act [21 U.S.C. 812], but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

Increased threat condition means an increase in the protective measure level, relative to the lowest protective measure level applicable to the site during the previous 60 days, as promulgated by an NRC Advisory.

Initial drug test means a test to differentiate "negative" specimens from those that require confirmatory drug testing.

Initial validity test means a first test used to determine whether a specimen is adulterated, dilute, substituted, or invalid, and may require confirmatory validity testing.

Invalid result means the result reported by an HHS-certified laboratory for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

Legal action means a formal action taken by a law enforcement authority or court of law, including an arrest, an indictment, the filing of charges, a conviction, or the mandated implementation of a plan for substance abuse treatment in order to avoid a permanent record of an arrest or conviction, in response to any of the following activities:

(1) The use, sale, or possession of illegal drugs;

(2) The abuse of legal drugs or alcohol; or

(3) The refusal to take a drug or alcohol test.

Licensee testing facility means a drug and specimen validity testing facility that is operated by a licensee or other entity who is subject to this part to perform tests of urine specimens.

Limit of detection (LOD) means the lowest concentration of an analyte that an analytical procedure can reliably detect, which could be significantly lower than the established cutoff levels.

Limit of quantitation (LOQ) means the lowest concentration of an analyte at which the concentration of the analyte can be accurately determined under defined conditions.

Maintenance means, for the purposes of §26.4(a)(4), the following onsite maintenance activities: Modification, surveillance, post-maintenance testing, and corrective and preventive maintenance.

Medical Review Officer (MRO) means a licensed physician who is responsible for receiving laboratory results generated by a Part 26 drug testing program and who has the appropriate medical training to properly interpret and evaluate an individual's drug and validity test results together with his or her medical history and any other relevant biomedical information.

Nominal means the limited flexibility that is permitted in meeting a scheduled due date for completing a recurrent activity that is required under this part, such as the nominal 12-month frequency required for FFD refresher training in §26.29(c)(2) and the nominal 12-month frequency required for certain audits in §26.41(c)(1). Completing a recurrent activity at a nominal frequency means that the activity may be completed within a period that is 25 percent longer or shorter than the period required in this part. The next scheduled due date would be no later than the current scheduled due date plus the required frequency for completing the activity.

Other entity means any corporation, firm, partnership, limited liability company, association, C/V, or other organization who is subject to this part under §26.3(a) through (c), but is not licensed by the NRC.

Oxidizing adulterant means a substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drugs or drug metabolites, or a substance that affects the reagents in either the initial or confirmatory drug test. Examples of these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI), bleach, iodine/iodide, halogens, peroxidase, and peroxide.

Positive result means, for drug testing, the result reported by a licensee testing facility or HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentration. A result reported by an HHS-certified laboratory that a specimen contains a drug or drug metabolite below the cutoff concentration is also a positive result when the laboratory has conducted the special analysis permitted in §26.163(a)(2). For alcohol testing, a positive result means the result reported by a collection site when the BAC indicated by testing a specimen exceeds the cutoff concentrations established in this part.

Potentially disqualifying FFD information means information demonstrating that an individual has—

(1) Violated a licensee's or other entity's FFD policy;

(2) Had authorization denied or terminated unfavorably under §§26.35(c)(2), 26.53(i), 26.63(d), 26.65(g), 26.67(c), 26.69(f), or 26.75(b) through (e);

(3) Used, sold, or possessed illegal drugs;

(4) Abused legal drugs or alcohol;

(5) Subverted or attempted to subvert a drug or alcohol testing program;

(6) Refused to take a drug or alcohol test;

(7) Been subjected to a plan for substance abuse treatment (except for self-referral); or

(8) Had legal action or employment action, as defined in this section, taken for alcohol or drug use.

Protected area has the same meaning as in §73.2(g) of this chapter: An area encompassed by physical barriers and to which access is controlled.

Quality control sample means a sample used to evaluate whether an analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative samples, and blind samples are collectively referred to as "quality control samples" and each is individually referred to as a "sample."

Questionable validity means the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid.

Reviewing official means an employee of a licensee or other entity specified in §26.3(a) through (c), who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not limited to, the results of a determination of fitness, as defined in §26.189, in order to determine whether the individual may be granted or maintain authorization.

Safety-related structures, systems, and components (SSCs) mean, for the purposes of this part, those structures, systems, and components that are relied on to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in 10 CFR 50.34(a)(1).

Security-related SSCs mean, for the purposes of this part, those structures, systems, and components that the licensee will rely on to implement the licensee's physical security and safeguards contingency plans that either are required under Part 73 of this chapter if the licensee is a construction permit applicant or holder or an early site permit holder, as described in §26.3(c)(3) through (c)(5), respectively, or are included in the licensee's application if the licensee is a combined license applicant or holder, as described in §26.3(c)(1) and (c)(2), respectively.

Shift cycle means a series of consecutive work shifts and days off that is planned by the licensee or other entity

to repeat regularly, thereby constituting a continuous shift schedule.

Standard means a reference material of known purity or a solution containing a reference material at a known concentration.

Strategic special nuclear material (SSNM) means uranium-235 (contained in uranium enriched to 20 percent or more in the uranium-235 isotope), uranium-233, or plutonium.

Substance abuse means the use, sale, or possession of illegal drugs, or the abuse of prescription and over-the-counter drugs, or the abuse of alcohol.

Substituted specimen means a specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology.

Subversion and subvert the testing process mean a willful act to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others at any stage of the testing process (including selection and notification of individuals for testing, specimen collection, specimen analysis, and test result reporting), and adulterating, substituting, or otherwise causing a specimen to provide an inaccurate test result.

Supervises or manages means the exercise of control over a work activity by an individual who is not directly involved in the execution of the work activity, but who either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity.

Ten (10)-hour shift schedule means a schedule that averages more than 9 hours, but not more than 11 hours, per workday over the entire shift cycle.

Transporter means a general licensee, under 10 CFR 70.20(a), who is authorized to possess formula quantities of SSNM, in the regular course of carriage for another or storage incident thereto, and includes the driver or operator of any conveyance, and the accompanying guards or escorts.

Twelve (12)-hour shift schedule means a schedule that averages more than 11 hours, but not more than 12 hours, per workday over the entire shift cycle.

Unit outage means, for the purposes of this part, that the reactor unit is disconnected from the electrical grid.

Validity screening test means a test to determine the need for initial validity testing of a urine specimen, using a non-instrumented test in which the endpoint result is obtained by visual evaluation (read by the human eye), or a test that is instrumented to the extent that results are machine-read.

Validity screening test lot means a group of validity screening tests that were made from the same starting material.

§ 26.7 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding on the Commission.

§ 26.8 Information collection requirements: OMB approval.

(a) The NRC has submitted the information collection requirements contained in this part for approval by the Office of Management and Budget (OMB), as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150–0146.

(b) The approved information collection requirements contained in this part appear in §§ 26.9, 26.27, 26.29, 26.31, 26.33, 26.35, 26.37, 26.39, 26.41, 26.53, 26.55, 26.57, 26.59, 26.61, 26.63, 26.65, 26.67, 26.69, 26.75, 26.77, 26.85, 26.87, 26.89, 26.91, 26.93, 26.95, 26.97, 26.99, 26.101, 26.103, 26.107, 26.109, 26.111, 26.113, 26.115, 26.117, 26.119, 26.125, 26.127, 26.129, 26.135, 26.137, 26.139, 26.153, 26.155, 26.157, 26.159, 26.163, 26.165, 26.167, 26.168, 26.169, 26.183, 26.185, 26.187, 26.189, 26.203, 26.205, 26.207, 26.211, 26.401, 26.403, 26.405, 26.406, 26.407, 26.411, 26.413, 26.415, 26.417, 26.711, 26.713, 26.715, 26.717, 26.719, and 26.821.